

Form 54 - Change of Medications

Data File: f54_ct_pub File Date: 07/20/2007 Structure: Multiple rows per participant Population: HT & CaD participants

Participant ID

Variable # 1 Usage Notes: none

Sas Name: ID

Sas Label: Participant ID Categories: Study: Administration

F54 Days since CT randomization

Variable # 2 Usage Notes: none

Sas Name: F54DAYS

Sas Label: F54 Days since CT randomization

Categories: Study: Administration

 N
 Min
 Max
 Mean
 Std Dev

 48589
 2
 3913
 1158.9761
 782.31583

F54 Days since CaD randomization

Days between CaD randomization and initiation of form

Variable # 3 Usage Notes: none

Sas Name: F54CADDY

Sas Label: F54 Days since CaD randomization

Categories: Study: Administration

N Min Max Mean Std Dev

37405 -741 3440 833.60618 781.53824

F54 Visit type

Variable # 4 Usage Notes: none

Sas Name: F54VTYP

Sas Label: Visit type Categories: Study: Administration

Values Ν % 2 Semi-Annual Visit 20.2% 9,838 3 Annual Visit 12,210 25.1% 4 Non-Routine Visit 26,516 54.6% 5 6 Week HRT/4 Week CaD Call 25 0.1%

48,589

F54 Visit year

Visit year for which this form was collected.

Variable # 5 Usage Notes: none

Sas Name: F54VY
Sas Label: Visit year

Categories: Study: Administration

 N
 Min
 Max
 Mean
 Std Dev

 22048
 1
 11
 3.82293
 2.07579

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F54 HRT dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) HRT dosage (pills/week):

Variable # 6 Usage Notes: none

Sas Name: HRT

Sas Label: HRT dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|-------|-----|-----|--------|---------|
| 28080 | 0 | 14 | 3.7909 | 3.34133 |

F54 CEE 0.3 mg dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) CEE 0.3 mg dosage (pills/week):

Variable # 7 Usage Notes: none

Sas Name: CEE3

Sas Label: CEE 0.3mg dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|-----|-----|-----|---------|---------|
| 492 | 0 | 14 | 4.62907 | 3.3704 |

F54 CEE 0.625 mg dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) CEE 0.625 mg dosage (pills/week):

Variable # 8 Usage Notes: none

Sas Name: CEE625

Sas Label: CEE 0.625 mg dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|-----|-----|-----|---------|---------|
| 441 | 0 | 14 | 4.36281 | 3.48844 |

F54 MPA 2.5 mg dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) MPA 2.5 mg dosage (pills/week):

Variable # 9 Usage Notes: none

Sas Name: MPA25

Sas Label: MPA 2.5 mg dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|------|-----|-----|---------|---------|
| 4014 | 0 | 56 | 6.55306 | 4.41765 |

F54 MPA 5 mg dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) MPA 5 mg dosage (pills/week):

Variable # 10 Usage Notes: none

Sas Name: MPA5

Sas Label: MPA 5 mg dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|-----|-----|-----|------|---------|
| 500 | 0 | 28 | 5.87 | 3.20306 |

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F54 MPA 10 mg dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) MPA 10 mg dosage (pills/week):

Variable # 11 Usage Notes: none

Sas Name: MPA10

Sas Label: MPA 10 mg dosage (pills/week)

Categories: Study Interventions: HRT Intervention/Management

| N | Min | Max | Mean | Std Dev |
|------|-----|-----|---------|---------|
| 1202 | 0 | 21 | 6.20424 | 4.14894 |

F54 CaD dosage (pills/week)

What is the new study medication schedule? (Include all study medications the participant should take, including those that you are not changing.) CaD dosage (pills/week):

Variable # 12 Usage Notes: none

Sas Name: CAD

Sas Label: CaD dosage (pills/week)

Categories: Study Interventions: CaD Intervention/Management

| N | Min | Max | Mean | Std Dev |
|-------|-----|-----|---------|---------|
| 28152 | 0 | 14 | 6.74861 | 5.68717 |

F54 Cyclic regimen

Is this a cyclic regimen?

Variable # 13 Usage Notes: Not collected on all versions of Form 54.

Sas Name: CYCLIC

Sas Label: Cyclic regimen

| Values | | N | % | | 0. 1.1 |
|--------|---------|--------|-------|-------------|--|
| 0 | No | 16,786 | 34.5% | Categories: | Study Interventions: HRT Intervention/Management |
| 1 | Yes | 506 | 1.0% | | |
| | Missing | 31,297 | 64.4% | | |
| | | 48,589 | | | |

F54 Study medication permanent

Is the new study medication schedule permanent?

Variable # 14 Usage Notes: none

Sas Name: PERM

Sas Label: Study medication permanent

Categories: Study Interventions: CaD Intervention/Management
Study Interventions: HPT Interventions/Management

Study Interventions: HRT Intervention/Management

 Values
 N
 %

 0
 No
 24,022
 49.4%

 1
 Yes
 23,978
 49.3%

 .
 Missing
 589
 1.2%

 48,589

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F54 How long to take (weeks)

For how long should the participant follow this new study medication schedule? (Record shortest length of time if more than one medication.)

Sas Name: HOWLONG pattern rule not applied).

Sas Label: How long to take (weeks)

Categories: Study Interventions: CaD Intervention/Management

Study Interventions: HRT Intervention/Management

Usage Notes: Sub-question of F54 V3 Q7 "Study medication permanent" (skip

| N | Min | Max | Mean | Std Dev |
|-------|-----|-----|---------|---------|
| 23046 | 0 | 52 | 9.33048 | 7.75506 |

F54 HRT - bleeding

Variable # 15

Why did you make the change in the medication schedule? (Mark all that apply). HRT - bleeding:

Variable # 16 Usage Notes: none

Sas Name: HRTBLEED

Sas Label: HRT - bleeding Categories: Study Interventions: HRT Intervention/Management

| Valu | ues | N | % |
|------|---------|--------|-------|
| 0 | No | 18,949 | 39.0% |
| 1 | Yes | 5,751 | 11.8% |
| | Missing | 23,889 | 49.2% |
| | | 48,589 | |

F54 HRT - biopsy abnormality

Why did you make the change in the medication schedule? (Mark all that apply). HRT - biopsy abnormality:

Variable # 17 Usage Notes: none

Sas Name: HRTBIOP

Sas Label: HRT - biopsy abnormality

Categories: Study Interventions: HRT Intervention/Management

| Values | | N | % |
|--------|---------|--------|-------|
| 0 | No | 24,481 | 50.4% |
| 1 | Yes | 219 | 0.5% |
| | Missing | 23,889 | 49.2% |
| | | 48,589 | |

F54 HRT - abnormal transvaginal ultrasound

Why did you make the change in the medication schedule? (Mark all that apply). HRT - abnormal transvaginal ultrasound:

Variable # 18 Usage Notes: none

Sas Name: HRTTVU

Sas Label: HRT - abnormal transvaginal ultrasound

Categories: Study Interventions: HRT Intervention/Management

 Values
 N
 %

 0
 No
 24,611
 50.7%

 1
 Yes
 89
 0.2%

 .
 Missing
 23,889
 49.2%

 48,589

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F54 HRT - symptom intolerance

Why did you make the change in the medication schedule? (Mark all that apply). HRT - symptom intolerance:

Variable # 19 Usage Notes: none

Sas Name: HRTSYMP

Sas Label: HRT - symptom intolerance

 Values
 N
 %

 0
 No
 19,964
 41.1%

 1
 Yes
 4,736
 9.7%

 .
 Missing
 23,889
 49.2%

 48,589

Categories: Study Interventions: HRT Intervention/Management

F54 HRT - other

Why did you make the change in the medication schedule? (Mark all that apply). HRT - other:

Variable # 20 Usage Notes: none

Sas Name: HRTOTHER

Sas Label: HRT - other

Categories: Study Interventions: HRT Intervention/Management

 Values
 N
 %

 0
 No
 9,515
 19.6%

 1
 Yes
 15,185
 31.3%

 .
 Missing
 23,889
 49.2%

 48,589

F54 CaD - symptom intolerance

Why did you make the change in the medication schedule? (Mark all that apply). CAD - symptom intolerance:

Variable # 21 Usage Notes: none

Sas Name: CADSYMP

Missing

Sas Label: CaD - symptom intolerance Categories: Study Interventions: CaD Intervention/Management

%

28.4%

18.2%

53.3%

 Values
 N

 0
 No
 13,812

 1
 Yes
 8,867

48,589

25,910

F54 CaD - other

Why did you make the change in the medication schedule? (Mark all that apply). CAD - other:

Variable # 22 Usage Notes: none

Sas Name: CADOTHER

Sas Label: CaD - other Categories: Study Interventions: CaD Intervention/Management

 Values
 N
 %

 0
 No
 8,194
 16.9%

 1
 Yes
 14,485
 29.8%

 .
 Missing
 25,910
 53.3%

 48,589

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